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10/608,978	06/26/2003	John D. Dobak III	103002	6407

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EXAMINER
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JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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06/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/608,978

Applicant(s)

DOBAK ET AL.

Examiner

Henry M. Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20, 2006 has been entered.

***Response to Arguments***

Applicant's arguments filed November 20, 2006 have been fully considered but they are not persuasive. Applicants argue that Amplantz fails to teach or suggest a device to treat tissue that includes the use of at least two radially extending tabs that are disposed around a circumference of the inner tube to substantially center the inner tube within the dual balloon. The argument cannot be addressed due to inconsistencies between the specification and the claims. The claims indicate the tabs are between the inner tube and the inner balloon. In such a position, the tabs would not be involved with fluid filling the first interior volume. The specification indicates the tabs center the inner tube in the catheter, with no specific mention of either balloon, and specifically cites as important to keep the inner and outer tubes from contacting each other. In this case, the tabs would be between the inner and outer tubes and in the flow to fill the first interior volume. However, the use of spacing between concentric catheter tubes is pervasive in the art and is neither inventive nor novel.

***Drawings***

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the position of the tabs as described in the specification. The drawings also fail to clearly show the

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fluid connection between lumen 118 and the second interior volume. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite due to indicated positioning of the tabs. To be in the path of the first interior volume filling fluid, the tabs must be positioned between the inner and outer tubes. The

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claims cite they are to center the inner tube within the balloon. It is unclear how the tabs can function to center the inner tube with the balloon. Further, the specification fails to positively associate the tabs with the balloons.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,868,735 to Lafontaine in view of U.S. Patent 5,106,360 to Ishiwara et al. and further in view of U.S. Patent 4,445,892 to Hussein et al. Lafontaine discloses a device to treat tissue comprising an outer tube (Fig. 2, # 28), an inner tube (Fig. 2, # 32) disposed at least partially within the outer tube and a dual balloon (Fig. 2, 14) and a lumen for a guidewire. A marker band is disclosed (Fig. 2, # 36). The inner and outer balloons are distally connected to the inner tube and the proximal end of the outer balloon is connected to the outer tube and the proximal end of the inner balloon is connected to the inner tube. The balloons form a volume

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between. The inner balloon has supply and return lumens disclosed, however they are exterior to the inner tube. The reversal of components in a prior art reference, where there is no disclosed significance to such reversal, is a design consideration within the skill of the art. In re Gazda, 219 F.2d 449, 104 USPQ 400 (CCPA 1955); In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). Lafontaine does not disclose a lumen to fill the volume between the balloons. Ishiwara et al. teach a catheter device with concentric balloons defining a volume between (Fig. 5) with a lumen in fluid connection with the volume (Fig. 5, # 30). The space interior to the inner balloon has both a supply and return lumen. Neither Lafontaine nor Ishiwara et al. teach spacers for maintaining position of elements. Hussein et al. disclose a dual balloon catheter (abstract) with inner and outer tubes wherein spacers are provided to center the inner tube within the outer tube and allow fluid flow around the inner tube (Fig 6, #s 308 & 310). Hussein et al. teach the use of perfluorocarbon for cooling and Lafontaine teaches the use of Freon. The collection of Lafontaine, Ishiwara et al. and Hussein et al. represent numerous features common in balloon catheters. It would have been obvious to one skilled in the art to combine the various features of Lafontaine, Ishiwara et al. and Hussein et al. to logically advance the art based on ordinary innovation.

"We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. See U. S. Const., Art. I, §8, cl. 8. These premises led to the bar on patents claiming obvious subject matter established in Hotchkiss and codified in

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§103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose" (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL.; SUPREME COURT OF THE UNITED STATES, No. 04-1350; ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT; April 30, 2007).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,868,735 to Lafontaine in view of U.S. Patent 5,106,360 to Ishiwara et al. and further in view of U.S. Patent 4,445,892 to Hussein et al. as applied to claim 8 above and further in view of U.S. Patent 6,063,101 to Jacobsen et al. Lafontaine, Ishiwara et al. and Hussein et al. teach all of the limitations of the claim except a fluid contrast media. Jacobsen et al. teach that it is old and well known in the art to provide a contrast media as an inflation fluid for a balloon catheter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a fluid contrast media in the invention of Lafontaine/Ishiwara et al. Hussein et al. in the fluid for inflating the balloon.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,868,735 to Lafontaine in view of U.S. Patent 5,106,360 to Ishiwara et al. and further in view of U.S. Patent 4,445,892 to Hussein et al. as applied to claim 8 above and further in view of U.S. Patent 6,497,721 to Ginsburg, et al. Lafontaine, Ishiwara et al. and Hussein et al. are discussed above, but do not teach specific pumps for the fluid delivery. Ginsburg et al. disclose a similar device and teach that it is old and well known in the art to use a variety of different pumps to circulate the heat exchange fluid (col. 24 lines 10-14). Each of the pumps disclosed by Ginsburg et al. may be substituted one for the other. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a gear pump for fluid delivery in the invention of Lafontaine/Ishiwara et al./Hussein et al. particularly in view of the teaching of Ginsburg et al. that a substitution as such would be proper.


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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Henry M. Johnson, III  
Primary Examiner  
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